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November 21, 1986

#11

Mr. Ronald Wilson
Office of the Associate Commissioner
for Health Affairs (HFY-20)
Room 11-46
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Duromedics Cardiac
Valve Prosthesis
FDA Docket # 86E-0460

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for Patent Extension of U. S. Patent No. 4,328,592 issued May 11, 1982. The application was filed on October 24, 1986 under Title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 USC 156(d)(2)(A).

C.E. Van Horn

Charles E. Van Horn
Director, Group 120
U.S. Patent and Trademark Office

cc: Mr. James J. Schumann
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